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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,593	11/29/2001	Seiji Sakano	KP8447DIV	2953

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EXAMINER	
MERTZ, PREMA MARIA	

ART UNIT	PAPER NUMBER
1646	9

DATE MAILED: 10/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/995,593	SAKANO ET AL.	
	Examiner	Art Unit	
	Prema M Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-87* is/are pending in the application.

4a) Of the above claim(s) *4-29 and 31-87* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group II (claims 1-3, 30) drawn to a method of treatment with human serrate-1 protein of amino acid sequence of SEQ ID NO:5, in Paper No. 8 (8/13/03) is acknowledged. The traversal is on the ground(s) that the restriction is improper since the examiner has not shown that examination of the major inventions of the various Groups would entail a serious burden. This is not found persuasive because the searches for the 10 different Groups would not overlap. Inventions 5 and 6 for example are independent and distinct, each from the other, because each of the nucleic acid molecules are materially different products which are structurally and chemically different, capable of separate manufacture and use. The products in the different Groups are physically and chemically distinct from each other, and if patentable would support separate patents. Distinctness is further shown because a search of one of the nucleic acid molecules would not reveal art pertinent to the other and each of these products could be made and used without any one or more of the other products. Separate searches would also be required for searching each of the protein products eg. a search of the literature for the protein of SEQ ID NO:2 would not necessarily reveal art for the protein of SEQ ID NO:5. Therefore, contrary to Applicants arguments that the nucleic acid, protein and methods of treatment claims are not related and are properly restrictable in accordance with MPEP. § 806.04 and MPEP. § 808.01.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter as defined by MPEP. § 808.02, the Examiner has *prima facie* shown a serious burden of search (see

MPEP. § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

The Groups as delineated in the restriction requirement (Paper No. 7, 7/30/03) are patentably distinct one from the other such that each invention could, by itself, in principle, support its own separate patent (as shown by the arguments put forth in the written restriction requirement).

The requirement is still deemed proper and is therefore made FINAL.

Claims 4-29, 31-87 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: a method of suppressing differentiation by administering a human serrate-1 polypeptide.

3. The abstract of the disclosure is objected to because there is no mention in the abstract of the human serrate-1 polypeptide and a method of treatment with such. Correction is required. See MPEP § 608.01(b).

Claim rejections-35 U.S.C. 112, first paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4a. Claims 1-3, 30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of suppressing differentiation of blood undifferentiated cells in vitro by comprising contacting a polypeptide comprising an amino acid sequence consisting of SEQ ID NO:5, does not reasonably provide enablement for a method for suppressing differentiation of all cells as recited in claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The instant specification is non-enabling for a method for suppressing differentiation of all types of undifferentiated cells in a patient and in vitro by administering a protein comprising an amino acid sequence set forth in SEQ ID NO:5. It is inconceivable, that administering the protein would prevent differentiation of nerve cells, muscle cells, skin cells, liver cells or lung cells. The text on page 47-54, Examples 10-13 of the instant specification supports the use of human serrate-1 protein on suppression of blood undifferentiated cells in vitro. However, the specification clearly fails to supply the guidance that would be needed by a routine practitioner to suppress differentiation of all types of cells in vitro and in vivo. The instant specification has also failed to disclose the duration and quantity of administration of the protein to a subject depending on the severity of the disease for treatment, which are important parameters. In the absence of this guidance, a practitioner would have to resort to a substantial amount of undue experimentation involving the variation in the amount and duration of administration of the protein in the method of the instant invention. The instant situation is directly analogous to that which was addressed in In re Colianni, 195 U.S.P.Q. 150, C.A.F.C., which held that a:

"disclosure that calls for application of 'sufficient' ultrasonic energy to practice claimed method of fusing bones but does not disclose what 'sufficient' dosage of ultrasonic energy might be or how those skilled in the art might select appropriate intensity, frequency, and duration, and contains no specific examples or embodiment by way of illustration of how claimed method is to be practiced does not meet requirements of 35 U.S.C. § 112 first paragraph".

In view of this unpredictability in suppression of differentiation of all types of cells in vitro and in vivo, there cannot be said to be any reasonable expectation of success at the *in vivo* application of the claimed method. Therefore, it would require undue experimentation for the ordinary artisan to determine how to use the claimed method.

The CAFC decision (Genentech Inc. v. Novo Nordisk, 42 USPQ2d 1001, 1997) expressly states that:

"When there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement".

If Applicants will kindly review page 1404 of In re Wands, they will find that the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

Given the breadth of claims 1-2, in light of the predictability of the art as determined by the number of working examples, the level of skill of the artisan, and the guidance provided in the instant specification and the prior art of record, it would require undue experimentation for one of skill in the art to practice the claimed invention.

Claim Rejections - 35 USC § 112, second paragraph

5. Claims 1-3, 30 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 30 are vague and indefinite because they recite non-elected subject matter. Appropriate correction is requested.

Claims 1 and 30 are vague and indefinite because they recite a method. However, there is no result step recited in the method, in the absence of which the recited method is incomplete.

Claim 2, line 3, recites "brain and nervous system" which is vague and indefinite because these cells are common cells.

Claims 2-3 are rejected as vague and indefinite insofar as they rely on claim 1 for its limitations.

Conclusion

No claims are allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (703) 746-5300.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
October 7, 2003